

U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

B/O Form PTO-1390

**Transmittal Letter to the United States  
Designated/Elected Office (DO/EO/US)  
Concerning a Filing Under 35 USC 371**

Attorney's Docket Number

SPEI3003/ESS

U.S. Application Number (if known)

**10/581595**

International Application Number

PCT/GB2004/005263

International Filing Date

15 December 2004

Priority Date Claimed

23 December 2003

Title of Invention

**PROCESS FOR PRODUCING PELLETS FOR PHARMACEUTICAL COMPOSITIONS**

Applicant(s) for DO/EO/US

Christopher SPEIRS, et al.

**Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items under 35 USC 371:**

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 USC 371.
  2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC 371.
  3. ☒ This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 371(b) and PCT Articles 22 and 39(1).
  4. ☐ The U.S. has been elected (Article 31).
  5. ☒ A copy of the International Application as filed 35 USC 371(c)(2).
    - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
    - b. ☐ has been transmitted by the International Bureau.
    - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
  6. ☐ A translation of the International Application into English (35 USC 371(c)(2)).
  7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3))
    - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
    - b. ☐ have been transmitted by the International Bureau.
    - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
    - d. ☐ have not been made and will not be made.
  8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)).
  9. ☐ An oath or declaration of the inventor(s) (35 USC 371(c)(4)). ( ☐ Executed ☐ Unexecuted)
  10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)).
- Items 11 to 16 below concern other document(s) or information included:**
11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
  12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
  13. ☒ A preliminary amendment.
  14. ☒ An Application Data Sheet under 37 CFR 1.76.
  15. ☐ A substitute specification.
  16. ☐ A change of power of attorney and/or address letter.
  17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and U.S.C. 1.821 - 1.825.
  18. ☒ A second copy of the published international application under 35 U.S.C. 154(d)(4).
  19. ☐ A second copy of the English translation of the international application under 35 U.S.C. 154(d)(4)
  20. ☒ Other items or information: Forms: PCT/RO/101; PCT/RO/105; PCT/IB/304; PCT/IB/306; Notification of Transmittal of & copies of Int'l Search Rpt & Written Opinion & assoc. refs; WO 2005/060938A1

|   |              |  |               |   |                |
|---|--------------|--|---------------|---|----------------|
| Application Number (if Known)<br><b>10/581595</b>   |              | International Application Number<br><b>PCT/GB2004/005263</b>                   |               | Attorney's Docket Number<br><b>SPEI3003/ESS</b> |                |
|   |              |  |               | <b>Calculations</b>                             | <b>PTO USE</b> |
| 21. The following fees are submitted:   |              |  |               |   |                |
| <input checked="" type="checkbox"/> a) Basic national fee.....\$300.00<br><input checked="" type="checkbox"/> b) Examination fee .....\$200.00  |              |  |               | \$500.00  |                |
| <input checked="" type="checkbox"/> c) Search Fee:<br><input type="checkbox"/> If the written opinion of the ISA/US or the International preliminary examination report prepared b IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....\$0.00<br><input type="checkbox"/> Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100.00<br><input checked="" type="checkbox"/> International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....\$400.00<br><input type="checkbox"/> All other situations.....\$500.00 |              |  |               | \$400.00  |                |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fractions thereof.   |              |  |               |   |                |
| Total Sheets  | Extra sheets | Number of each additional 50 or fractions thereof (round up to a whole number) | RATE          |   |                |
| - 100 =   | /50=         |  | x \$250.00    |   |                |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).  |              |  |               | \$ 130.00                                       |                |
| CLAIMS  | NUMBER       | NUMBER EXTRA   | RATE          |   |                |
| Total Claims  | 22 -20 =     | 2  | x \$50.00     | \$ 100.00                                       |                |
| Independent Claims  | -3 =         |  | x \$200.00    |   |                |
| Multiple Dependent Claims (if applicable)   |              |  | + \$360.00    |   |                |
| <b>TOTAL OF ABOVE CALCULATIONS</b>  |              |  |               | <b>\$ 1,130.00</b>                              |                |
| <input type="checkbox"/> Reduction by 1/2 for filing by small entity, if applicable. Small Entity Status is asserted pursuant to 37 CFR 1.27 for this application.  |              |  |               | \$ 565.00                                       |                |
| <b>SUBTOTAL</b>   |              |  |               | <b>\$ 565.00</b>                                |                |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).   |              |  |               |   |                |
| <b>TOTAL NATIONAL FEE</b>   |              |  |               | <b>\$ 565.00</b>                                |                |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property.   |              |  |               |   |                |
| <b>TOTAL FEES ENCLOSED</b>  |              |  |               | <b>\$ 565.00</b>                                |                |
|   |              |  | Amount to be: | Refunded:                                       |                |
|   |              |  |               | Charged:  |                |

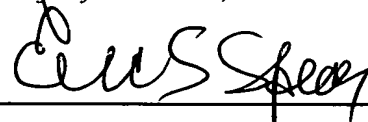
- a. ☒ A check in the amount of **\$ 565.00** to cover the fees is enclosed. (Check No. 48430)  
 b. ☐ Please charge my **Deposit Account Number 02-0200** in the amount of **\$** \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.  
 c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to **Deposit Account Number 02-0200**. A duplicate copy of this sheet is enclosed.

Note: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

**23364** - Customer Number  
 Phone: (703) 683-0500

DATE: June 5, 2006

Respectfully submitted,



Eric S. Spector  
 Attorney for Applicant  
 Registration Number: 22,495